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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,955	09/28/2001	Juan J. Perez-Villar	D0029 NP	4833

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EXAMINER	
MERTZ, PREMA MARIA	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 05/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/966,955	PEREZ-VILLAR ET AL.	
	Examiner	Art Unit	
	Prema M. Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-35 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group 1. Claims 1-10, 14-15, 34, are drawn to a nucleic acid encoding a protein of amino acid sequence set forth in SEQ ID NO:2, a vector, a host cell and a process for producing the receptor polypeptide, classified in Class 435, subclass 69.1.

Group 2. Claims 1-10, 14-15, 34, are drawn to a nucleic acid encoding a protein of amino acid sequence set forth in SEQ ID NO:4, a vector, a host cell and a process for producing the receptor polypeptide, classified in Class 435, subclass 69.1.

Group 3. Claims 1-10, 14-15, 34, are drawn to a nucleic acid encoding a protein of amino acid sequence set forth in SEQ ID NO:6, a vector, a host cell and a process for producing the receptor polypeptide, classified in Class 435, subclass 69.1.

Group 4. Claims 11-12, 16, 20, 35, are drawn to a polypeptide of amino acid sequence set forth in SEQ ID NO:2, classified in Class 530, subclass 350.

Group 5. Claims 11-12, 16, 20, 35, are drawn to a polypeptide of amino acid sequence set forth in SEQ ID NO:4, classified in Class 530, subclass 350.

Group 6. Claims 11-12, 16, 20, 35, are drawn to a polypeptide of amino acid sequence set forth in SEQ ID NO:6, classified in Class 530, subclass 350.

Group 7. Claim 13 is drawn to an antibody to a polypeptide of amino acid sequence set forth in SEQ ID NO:2, classified in Class 530, subclass 387.9.

Group 8. Claim 13 is drawn to an antibody to a polypeptide of amino acid sequence set forth in SEQ ID NO:4, classified in Class 530, subclass 387.9.

Group 9. Claim 13 is drawn to an antibody to a polypeptide of amino acid sequence set forth in SEQ ID NO:6, classified in Class 530, subclass 387.9.

Group 10. Claims 17, 29, 30, are drawn to a method of treating a condition by administering a polypeptide of amino acid sequence set forth in SEQ ID NO:2, classified in Class 514, subclass 2.

Group 11. Claims 17, 29-30, are drawn to a method of treating a condition by administering a polypeptide of amino acid sequence set forth in SEQ ID NO:4, classified in Class 514, subclass 2.

Group 12. Claims 17, 29-30 are drawn to a method of treating a condition by administering a polypeptide of amino acid sequence set forth in SEQ ID NO:6, classified in Class 514, subclass 2.

Group 13. Claim 17 is drawn to a method of treatment by administering the nucleic acid encoding the polypeptide of amino acid sequence set forth in SEQ ID NO:2, classified in Class 514, subclass 44.

Group 14. Claim 17 is drawn to a method of treatment by administering the nucleic acid encoding the polypeptide of amino acid sequence set forth in SEQ ID NO:4, classified in Class 514, subclass 44.

Group 15. Claim 17 is drawn to a method of treatment by administering the nucleic acid encoding the polypeptide of amino acid sequence set forth in SEQ ID NO:6, classified in Class 514, subclass 44.

Group 16.Claim 18, is drawn to a method of diagnosing a pathological condition using the nucleic acid encoding the polypeptide of amino acid sequence set forth in SEQ ID NO:2, classified in Class 435, subclass 6.

Group 17.Claim 18, is drawn to a method of diagnosing a pathological condition using the nucleic acid encoding the polypeptide of amino acid sequence set forth in SEQ ID NO:4, classified in Class 435, subclass 6.

Group 18.Claim 18, is drawn to a method of diagnosing a pathological condition using the nucleic acid encoding the polypeptide of amino acid sequence set forth in SEQ ID NO:6, classified in Class 435, subclass 6.

Group 19.Claim 19, 25, is drawn to a method of diagnosing a pathological condition using an antibody to the polypeptide of amino acid sequence set forth in SEQ ID NO:2, classified in Class 435, subclass 7.1.

Group 20.Claim 19, 25, is drawn to a method of diagnosing a pathological condition using an antibody to the polypeptide of amino acid sequence set forth in SEQ ID NO:4, classified in Class 435, subclass 7.1.

Group 21.Claim 19, 25, is drawn to a method of diagnosing a pathological condition using an antibody to the polypeptide of amino acid sequence set forth in SEQ ID NO:6, classified in Class 435, subclass 7.1.

Group 22.Claim 21, is drawn to a method of identifying a biological activity of the polypeptide of amino acid sequence set forth in SEQ ID NO:2, 4, or 6, Class and subclass undeterminable.

Group 23.Claims 22-23, 26-28 are drawn to a method for identifying a compound that modulates the activity of the polypeptide of amino acid sequence set forth in SEQ ID NO:2, 4, or 6 classified in Class 435, subclass 7.1.

Group 24.Claim 24 is drawn to a compound that modulates the activity of the polypeptide of amino acid sequence set forth in SEQ ID NO:2, 4, Class and subclass undeterminable.

Group 25.Claims 31-32 are drawn to a method for identifying a compound that enhances, increases or accelerates binding of a polypeptide of amino acid sequence set forth in SEQ ID NO:2, 4 or 6 with a cell signaling protein, classified in Class 435, subclass 7.1.

Group 26.Claim 33 is drawn to a method for identifying a compound that inhibits the phosphorylation of a polypeptide of amino acid sequence set forth in SEQ ID NO:2, 4 or 6 with a cell signaling protein, classified in Class 435, subclass 7.1.

Applicants are advised that claim 17 is an improper Markush claim because the multiple elements recited therein are polypeptides and nucleic acids which do not share a common technical feature which is based on a common property or special technical feature not found in the prior art. These polypeptides and nucleic acids are independent and distinct chemical compounds lacking either a common structural property which distinguishes them as group from structurally related compounds of the prior art or which provides them with a common utility which is lacking from those prior art polypeptides or nucleic acids.

Should any one of the Groups from 1-21 be elected, Applicant is required to select one polypeptide (one amino acid sequence) as set forth in SEQ ID NO:2, 4, or 6. Once one

polypeptide sequence is selected, all the other polypeptide sequences will be withdrawn from consideration.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products appear to constitute patentably distinct inventions for the following reasons:

Inventions 1-9, are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent utility, that is distinct for each invention which cannot be exchanged. The polynucleotides of inventions 1-3 can be used to make hybridization probes or can be used in gene therapy as well as in the production of the specific proteins of interest. The proteins of inventions 4-6 can be used as probes, or used therapeutically or diagnostically, e.g. in screening. The antibodies of inventions 7-9 can be used to obtain the polynucleotides of Groups I-3, and can also be used in diagnostics, e.g. as a probe in immunoassays. Each of the polynucleotides of inventions I-3 can be used to produce the specific polypeptides of Groups 4-6, respectively. The polynucleotide of Group I can only be used to produce the protein of Group 4 but not the proteins of Groups 5-6.

Inventions I-3 and 4-6 are related as processes of making and products made. The inventions are distinct if either or both of the following can be shown: (1) that the process as

claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case each of the proteins can be prepared by materially different processes, such as by chemical synthesis, or obtained from nature using various isolation and purification protocols.

Inventions 4-6 and 10-12, 22-23, 25-26, are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the products of inventions 4-6 can also be used as an antigens in the production of specific antibodies.

Inventions I-3 and 13-18 are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the products of inventions I-3 can also be used in production of the specific protein of interest.

Inventions 7-9 and 19-21 are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the products of inventions 7-9 can also be used in immunochromatography.

Inventions 1-3, 10-12, 19-21, 22-23, 25-26 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions 4-6 and 13-19 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions 7-9 and 10-18, 22-23, 25-26 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. 806.05 for inventive groups that are directed to <u>different</u> methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons:

Inventions 13-23, 25-26 are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different classification, different starting materials, process steps and goals. For example, invention 10 requires search and

consideration of therapeutic efficacy of administering a protein of amino acid sequence set forth in SEQ ID NO:2, which protein is not required by the methods of any of the other Groups. Therefore, a search and examination of all the methods in one patent application would result in an undue burden.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has *prima facie* shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

2. ***Election of Species***

This application contains claims directed to the following patentably distinct species of conditions of the claimed invention:

Applicants are required to elect one of the following species of conditions selected from:

(i) hyperactivity of B-lymphocytes;

(ii) hyperactivity of T-lymphocytes;

(iii) inhibiting T-cell lymphoma;

(iv) inhibiting T-cell tumor; and

(v) inhibiting T-cell thymoma.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of condition for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 17 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the

product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Prema Mertz

Prema Mertz Ph.D., J.D.
Primary Examiner
Art Unit 1646
May 8, 2006